

AMENDED IN ASSEMBLY AUGUST 15, 2016

AMENDED IN ASSEMBLY AUGUST 1, 2016

AMENDED IN SENATE MAY 31, 2016

SENATE BILL

No. 1095

Introduced by Senator Pan

(Coauthors: Senators Beall, McGuire, and Nielsen)

(Coauthors: Assembly Members Chiu, Gomez, *Gonzalez*, Maienschein,
and Rodriguez)

February 17, 2016

An act to amend Sections 124977 and 125001 of the Health and Safety Code, relating to public health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as amended, Pan. Newborn screening program.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing.

Existing law establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening tests, and states the intent of the Legislature that all costs of the genetic disease testing program be fully supported by fees paid for newborn screening tests, which are deposited in the GDTF. Existing law also authorizes moneys in the GDTF to be used for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, severe combined immunodeficiency (SCID), and adrenoleukodystrophy (ALD) and exempts the expansion of contracts for this purpose from certain provisions of the Public Contract Code,

the Government Code, and the State Administrative Manual, as specified.

This bill would require the department to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples as soon as *practicable, but no later than 2 years after* the disease is adopted by the federal Recommended Uniform Screening Panel ~~(RUSP)~~: *(RUSP), or enrollment of this bill, whichever is later*. By expanding the purposes for which moneys from the GDTF may be expended, this bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124977 of the Health and Safety Code
2 is amended to read:

3 124977. (a) It is the intent of the Legislature that, unless
4 otherwise specified, the genetic disease testing program carried
5 out pursuant to this chapter be fully supported from fees collected
6 for services provided by the program.

7 (b) (1) The department shall charge a fee to all payers for any
8 tests or activities performed pursuant to this chapter. The amount
9 of the fee shall be established by regulation and periodically
10 adjusted by the director in order to meet the costs of this chapter.
11 Notwithstanding any other law, any fees charged for prenatal
12 screening and followup services provided to persons enrolled in
13 the Medi-Cal program, health care service plan enrollees, or
14 persons covered by health insurance policies, shall be paid in full
15 and deposited in the Genetic Disease Testing Fund or the Birth
16 Defects Monitoring Program Fund consistent with this section.

17 (2) The department shall expeditiously undertake all steps
18 necessary to implement the fee collection process, including
19 personnel, contracts, and data processing, so as to initiate the fee
20 collection process at the earliest opportunity.

21 (3) Effective for services provided on and after July 1, 2002,
22 the department shall charge a fee to the hospital of birth, or, for
23 births not occurring in a hospital, to families of the newborn, for
24 newborn screening and followup services. The hospital of birth
25 and families of newborns born outside the hospital shall make
26 payment in full to the Genetic Disease Testing Fund. The

1 department shall not charge or bill Medi-Cal beneficiaries for
2 services provided pursuant to this chapter.

3 (4) (A) The department shall charge a fee for prenatal screening
4 to support the pregnancy blood sample storage, testing, and
5 research activities of the Birth Defects Monitoring Program.

6 (B) The prenatal screening fee for activities of the Birth Defects
7 Monitoring Program shall be ten dollars (\$10).

8 (5) The department shall set guidelines for invoicing, charging,
9 and collecting from approved researchers the amount necessary
10 to cover all expenses associated with research application requests
11 made pursuant to this section, data linkage, retrieval, data
12 processing, data entry, reinventory, and shipping of blood samples
13 or their components, and related data management.

14 (6) The only funds from the Genetic Disease Testing Fund that
15 may be used for the purpose of supporting the pregnancy blood
16 sample storage, testing, and research activities of the Birth Defects
17 Monitoring Program are those prenatal screening fees assessed
18 and collected prior to the creation of the Birth Defects Monitoring
19 Program Fund specifically to support those Birth Defects
20 Monitoring Program activities.

21 (7) The Birth Defects Monitoring Program Fund is hereby
22 created as a special fund in the State Treasury. Fee revenues that
23 are collected pursuant to paragraph (4) shall be deposited into the
24 fund and shall be available upon appropriation by the Legislature
25 to support the pregnancy blood sample storage, testing, and
26 research activities of the Birth Defects Monitoring Program.
27 Notwithstanding Section 16305.7 of the Government Code, interest
28 earned on funds in the Birth Defects Monitoring Program Fund
29 shall be deposited as revenue into the fund to support the Birth
30 Defects Monitoring Program.

31 (c) (1) The Legislature finds that timely implementation of
32 changes in genetic screening programs and continuous maintenance
33 of quality statewide services requires expeditious regulatory and
34 administrative procedures to obtain the most cost-effective
35 electronic data processing, hardware, software services, testing
36 equipment, and testing and followup services.

37 (2) The expenditure of funds from the Genetic Disease Testing
38 Fund for these purposes shall not be subject to Section 12102 of,
39 and Chapter 2 (commencing with Section 10290) of Part 2 of
40 Division 2 of, the Public Contract Code, or to Division 25.2

1 (commencing with Section 38070) of this code. The department
2 shall provide the Department of Finance with documentation that
3 equipment and services have been obtained at the lowest cost
4 consistent with technical requirements for a comprehensive
5 high-quality program.

6 (3) The expenditure of funds from the Genetic Disease Testing
7 Fund for implementation of the Tandem Mass Spectrometry
8 screening for fatty acid oxidation, amino acid, and organic acid
9 disorders, and screening for congenital adrenal hyperplasia may
10 be implemented through the amendment of the Genetic Disease
11 Branch Screening Information System contracts and shall not be
12 subject to Chapter 3 (commencing with Section 12100) of Part 2
13 of Division 2 of the Public Contract Code, Article 4 (commencing
14 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title
15 2 of the Government Code, and any policies, procedures,
16 regulations, or manuals authorized by those laws.

17 (4) The expenditure of funds from the Genetic Disease Testing
18 Fund for the expansion of the Genetic Disease Branch Screening
19 Information System to include cystic fibrosis, biotinidase, severe
20 combined immunodeficiency (SCID), adrenoleukodystrophy
21 (ALD), and any other disease that is detectable in blood samples,
22 as specified in subdivision (d) of Section 125001, may be
23 implemented through the amendment of the Genetic Disease
24 Branch Screening Information System contracts, and shall not be
25 subject to Chapter 2 (commencing with Section 10290) or Chapter
26 3 (commencing with Section 12100) of Part 2 of Division 2 of the
27 Public Contract Code, Article 4 (commencing with Section 19130)
28 of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government
29 Code, or Sections 4800 to 5180, inclusive, of the State
30 Administrative Manual as they relate to approval of information
31 technology projects or approval of increases in the duration or
32 costs of information technology projects. This paragraph shall
33 apply to the design, development, and implementation of the
34 expansion, and to the maintenance and operation of the Genetic
35 Disease Branch Screening Information System, including change
36 requests, once the expansion is implemented.

37 (d) (1) The department may adopt emergency regulations to
38 implement and make specific this chapter in accordance with
39 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division
40 3 of Title 2 of the Government Code. For the purposes of the

1 Administrative Procedure Act, the adoption of regulations shall
2 be deemed an emergency and necessary for the immediate
3 preservation of the public peace, health and safety, or general
4 welfare. Notwithstanding Chapter 3.5 (commencing with Section
5 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
6 these emergency regulations shall not be subject to the review and
7 approval of the Office of Administrative Law. Notwithstanding
8 Sections 11346.1 and 11349.6 of the Government Code, the
9 department shall submit these regulations directly to the Secretary
10 of State for filing. The regulations shall become effective
11 immediately upon filing by the Secretary of State. Regulations
12 shall be subject to public hearing within 120 days of filing with
13 the Secretary of State and shall comply with Sections 11346.8 and
14 11346.9 of the Government Code or shall be repealed.

15 (2) The Office of Administrative Law shall provide for the
16 printing and publication of these regulations in the California Code
17 of Regulations. Notwithstanding Chapter 3.5 (commencing with
18 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
19 Code, the regulations adopted pursuant to this chapter shall not be
20 repealed by the Office of Administrative Law and shall remain in
21 effect until revised or repealed by the department.

22 (3) The Legislature finds and declares that the health and safety
23 of California newborns is in part dependent on an effective and
24 adequately staffed genetic disease program, the cost of which shall
25 be supported by the fees generated by the program.

26 SEC. 2. Section 125001 of the Health and Safety Code is
27 amended to read:

28 125001. (a) The department shall establish a program for the
29 development, provision, and evaluation of genetic disease testing,
30 and may provide laboratory testing facilities or make grants to,
31 contract with, or make payments to, any laboratory that it deems
32 qualified and cost effective to conduct testing or with any metabolic
33 specialty clinic to provide necessary treatment with qualified
34 specialists. The program shall provide genetic screening and
35 followup services for persons who have the screening.

36 (b) The department shall expand statewide screening of
37 newborns to include tandem mass spectrometry screening for fatty
38 acid oxidation, amino acid, organic acid disorders, and congenital
39 adrenal hyperplasia as soon as possible. The department shall
40 provide information with respect to these disorders and available

1 testing resources to all women receiving prenatal care and to all
2 women admitted to a hospital for delivery. If the department is
3 unable to provide this statewide screening by August 1, 2005, the
4 department shall temporarily obtain these testing services through
5 a competitive bid process from one or more public or private
6 laboratories that meet the department's requirements for testing,
7 quality assurance, and reporting. If the department determines that
8 contracting for these services is more cost effective, and meets the
9 other requirements of this chapter, than purchasing the tandem
10 mass spectrometry equipment themselves, the department shall
11 contract with one or more public or private laboratories.

12 (c) The department shall expand statewide screening of
13 newborns to include screening for severe combined
14 immunodeficiency (SCID) as soon as possible. In implementing
15 the SCID screening test, the department shall also screen for other
16 T-cell lymphopenias that are detectable as a result of screening
17 for SCID, insofar as it does not require additional costs or
18 equipment beyond that needed to test for SCID.

19 (d) The department shall expand statewide screening of
20 newborns to include screening for adrenoleukodystrophy (ALD)
21 and any other disease that is detectable in blood samples as soon
22 as *practicable, but no later than two years after* the disease is
23 adopted by the federal Recommended Uniform Screening Panel
24 ~~(RUSP)~~. *(RUSP), or enrollment of the act amending this*
25 *subdivision, whichever is later.*